DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEC 16 1997

Ms. Linda A. Moline
Dynamic Healthcare Technologies, Inc.
101 Southhall Lane, Suite 210
Maitland, FL 32751

Reference: BK960041
Product: Transfusion Service Manger, Version 4.1.6
Date Received: March 29, 1996
Classification: Unclassified

Dear Ms. Moline:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and have determined that the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act that include requirements for registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Although your device has been determined to be "substantially equivalent," there are deficiencies in documentation that should be addressed before submitting a future premarket notification for this or a similar device. We are including suggestions for improvement for your consideration as you modify or upgrade this software package or design additional software. For future guidance, please refer to "Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software," dated January 13, 1997.

The Food and Drug Administration (FDA) accepted user validation information in lieu of the actual beta testing for this submission only. Blood establishment software vendors are responsible for suppling the test plan to the beta site(s) to ensure that all safety critical intended use functions have been included in the system level testing performed in the user's

environment and to evaluate the results of this testing prior to the final distribution of the software. FDA expects Dynamic Healthcare Technologies, Inc. to include this type of beta testing in the verification, validation, and testing section of the 510(k) notification for future submissions.

If your device has been classified into either class II (Special Controls) or class III (Premarket Approval), (see above), it may be subject to the above and additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note that this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or regulations.

This letter will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a legally marketed predicate device permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice on promotional labeling and advertisement for your device, please contact our Advertising and Promotional Labeling Staff (HFM-202) at (301) 594-2084.

Sincerely,

Jay S. Epstein, M.D.
Director
Office of Blood Research and Review
Center for Biologics
Evaluation and Research